REMARKS

Reconsideration of this application, as amended, is respectfully requested. Claims 1 and 6 have been amended. Claim 2 has been cancelled. All amendments are made without prejudice or disclaimer, and do not introduce any new subject matter. Applicants reserve the right to prosecute such cancelled claims or any other unclaimed subject matter in a later application. Consideration and entry of these amendments and remarks is respectfully requested.

Rejections under 35 U.S.C. 102(a)

Claims 1, 2, 6, and 7 stand rejected under 35 U.S.C. 102(a) as being anticipated by Dadsetan et al. (J. Cont. Rel. 93: 259-270 (2003)). Claim 2 has been cancelled; the rejection as to this claim is therefore moot. Applicants respectfully disagree with the rejection of claims 1, 6, and 7 and traverse the same as described below.

Dadsetan does not comprise a device with poly(ethylene carboxylate) (PEC) film on its surface, as in Applicants' previous claim 2 and amended claim 1. The cited sections of Dadsetan merely describe the insertion of a PEC film into a wire mesh cage to measure the biological response against the PEC. The reference is completely silent as to "device comprising a surface coated with a biodegradable polymer". As such, Dadsetan cannot anticipate Applicants' claimed subject matter. Withdrawal of this rejection is therefore respectfully requested.

Rejections under 35 U.S.C. 102(b)

Claims 1-5 and 14 stand rejected under 35 U.S.C. 102(b) as being anticipated by Acemoglu et al. (WO 1995/006007). Claim 2 has been cancelled; the rejection as to this claim is therefore moot. Applicants respectfully disagree with the rejection of claims 1, 3-5, and 15 and traverse the same as described below.

The Office Action notes that Applicants' specification broadly defines the term "device" such that microparticles of the biodegradable polymer *per se* are encompassed thereby. Applicants respectfully disagree that the skilled artisan would not read the term as broadly as suggested in the Office Action. Amended claim 1 relates to a "device comprising a surface coated with a biodegradable polymer". As described in Applicants' specification:

. . . it has now been found that a superior medical device implantable into the human or animal body may be obtained by coating the device with a biodegradable polymer . . . . (paragraph 0011)

In a further aspect, the invention provides a device coated with a co-polymer as defined herein. . . . (para. 0069)

In a further aspect the invention provides a drug delivery device or system comprising a medical device . . . coated with the polymer as described herein. . . . (para. 0089)

In yet a further aspect the invention provides a device coated with a polymer as defined herein above for in any method as defined under (i) to (x). (para. 0091)

In a further aspect there is provided a process for the production of the device of the invention comprising coating the device with the ethylene carbonate polymer defined herein. (para. 0093)

For example, the pharmacologically active agent(s) may be incorporated into the polymer or polymeric matrix of the invention. . .and sprayed onto the outer surface of the stent. (para. 0094)

In an alternative embodiment of the invention there is provided a process for the production of the device of the invention wherein the device is pre-covered with a polymer, e.g., a biocompatible and/or non-biodegradable polymer, and then covered with the polymer of the invention containing the drug dissolved, dispersed or suspended therein. (para. 0095)

1.21 g PEC and 50 mg Compound I are dissolved in 10 ml methylene chloride. This solution is sprayed onto the stent. After drying using a defined gas flow or vacuum, a defined polymer/drug film remains on the stent. (para. 0106, Example 1)

The flexibly PEC coated stent shows a surface without any signs of degradation (FIG. 1(A,B)). . . . (para 0109, Example 2)

> Compound I is incorporated into the solution of PEC or PLGA before forming a polymer matrix covering the outer surface of the stents. (para. 0111, Example 2C)

Thus, the specification clearly defines the "device" and the coating as two separate components. Even if the device comprises microparticles as suggested by the Office Action, it must still further include a separate coating comprising the specific biodegradable polymer of the claims. The Office Action does not point to any teaching by Acemoglu of a biodegradable polymer coating upon, as opposed to within, a device. As described in the Office Action, Acemoglu describes PEC microparticles comprising rhIL-6 therein. As such, Acemoglu cannot anticipate Applicants' claimed subject matter. Withdrawal of this rejection is therefore respectfully requested.

Rejections under 35 U.S.C. 103(a)

A. Rejection of claims 1-7 and 14 over Dadestan in view of Acemoglu

Claims 1-7 and 14 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Dadestan in view of Acemoglu. Claim 2 has been cancelled; the rejection as to this claim is therefore moot. Applicants respectfully disagree with the rejection of pending claims 1, 3-5, and 14 and traverse the same as described below.

Applicants' amended claims relate to a device that is coated with a biodegradable polymer. The Office Action alleges that Dadestan does not disclose "an additional pharmaceutically active agent" and that Acemoglu "does not teach application to a stent". The Office Action also alleges that Dadestan teaches "coating a stent". However, as described above, Dadestan reference merely demonstrates the insertion of PEC into, but not onto, a wire cage. As the Office Action admits, Acemoglu "does not teach application to a stent". Thus, neither reference teaches or suggests coating a device with a biodegradable polymer. Accordingly, a *prima facie* case of obviousness has not been and cannot be made from the combination of Dadestan and Acemoglu. As such, withdrawal of these rejections is respectfully requested.

B. Rejection of claims 1-7 and 14 over Roorda (U.S. Pub. No. 2001/0007083)

Claims 1-7 and 14 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Roorda. Claim 2 has been cancelled; the rejection as to this claim is therefore moot. Applicants respectfully disagree with the rejection of pending claims 1, 3-5, and 14 and traverse the same as described below.

The USTPO is required to establish a *prima facie* case of obviousness, and has not. As stated at MPEP 2141:

> Once the *Graham* factual inquiries are resolved, Office personnel must determine whether the claimed invention would have been obvious to one of ordinary skill in the art. . . .
>
> The key to supporting any rejection under 35 U.S.C. 103 is the clear articulation of the reason(s) why the claimed invention would have been obvious. The Supreme Court in *KSR* noted that the analysis supporting a rejection under 35 U.S.C. 103 should be made explicit. The Court quoting *In re Kahn,* 441 F.3d 977, 988, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006), stated that "'[R]ejections on obviousness cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.'" *KSR*, 550 U.S. at ___, 82 USPQ2d at 1396.

The instant rejections are improper. The Office Action does not address the *Graham* factual inquiries as required. Id. And the Office Action merely provides conclusions without any "articulated reasoning with some rational underpinning to support the legal conclusion of obviousness". Id. The Office Action alleges that it would have been obvious to skilled artisan "when fabricating the drug laden coated stent of Roorda to pick and choose from among the disclosed drug carrying materials, such as pol(ethylene) carbonate, given it would be selected for its disclosed function." The mere fact that the prior art may be modified does not make the modification obvious unless the prior art suggests the desirability thereof, and the Office Action is completely silent on this issue. In re Lalu, 747 F.2d 703, 223 USPQ 1257 (Fed. Cir. 1984). The Office Action does not cite any support for the conclusions therein. This line or reasoning is wholly inadequate to support an obviousness rejection.

The reasoning provided in the Office Action simply cannot serve as the basis for a proper obviousness rejection. Thus, Applicants believe that the Office Action has not established a *prima facie* case of obviousness of the pending claims and therefore respectfully request its withdrawal.

C. Rejection of claims 1-7 and 14 over Kowaguchi et al. (Chem. Pharm. Bull. 31(4): 1400-1403 (1983)

Claims 1-7 and 14 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Dadestan in view of Kowaguchi. Claim 2 has been cancelled; the rejection as to this claim is therefore moot. Applicants respectfully disagree with the rejection of pending claims 1, 3-5, and 14 and traverse the same as described below.

The Office Action alleges that Kawaguchi teaches "sutures and surgical implants were well known to be coated by biodegradable polymers" and that "poly(ethylene carbonate) has favorable biodegradation rates in vivo" but does not teach a PEC "drug loaded coated stent as a specifically disclosed embodiment." Finally, the Office Action alleges that it would have been obvious to coat sutures and surgical implants with PEC "given its favorable properties for such a use." Applicants respectfully disagree and believe the skilled artisan would read Kawaguchi in a much more limited way.

Kawaguchi relates to implanted pellets and does not suggest the use of PEC as a coating. As described at p. 1400:

> In this study, pellets of poly(ethylene carbonate) and poly(propylene carbonate) or pellets made of mixtures of the two copolymers were implanted into the peritoneal cavity of rats, in order to examine the biodegradability of the polymers.

There is no suggestion by Kawaguchi to coat any type of device, including a suture or a surgical implant. Kawaguchi's reference to "increasing interest" in "sutures, and surgical implant materials" is not an indication that the same "were well known to be coated by biodegradable polymers" as alleged in the Office Action. Kawaguchi merely states that such polymers were of interest for "specialized application" and does not suggest the use of coatings. The Office Action does not describe a link between Kawaguchi and the specific biodegradable polymers described in Applicants' claim 1. As described above, the USPTO is required to provide "a convincing line of reasoning as to why the artisan would have found the claimed invention to have been obvious in light of the teachings of the references." MPEP 2141. The Office Action simply concludes that Kawaguichi's PEC compositions (e.g, pellets) and reference to the "increasing interest" in the use of biodegradable polymers in "specialized applications" relating to "sutures, and surgical implant materials" would have rendered Applicants' claimed invention obvious. The reasoning provided in the Office Action is at least in part scientifically incorrect, is not clearly explained, and is an improper basis for an obviousness rejection. Thus, Applicants believe that the Examiner has not established a *prima facie* case of obviousness of the pending claims and therefore respectfully request withdrawal of the same.

CONCLUSIONS

Consideration and entry of these amendments and remarks are respectfully requested. Applicants believe the claims are now in condition for allowance and request that a Notice of Allowance be issued as soon as possible. Should the Examiner have any questions, please contact the undersigned attorney.

Respectfully submitted,

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